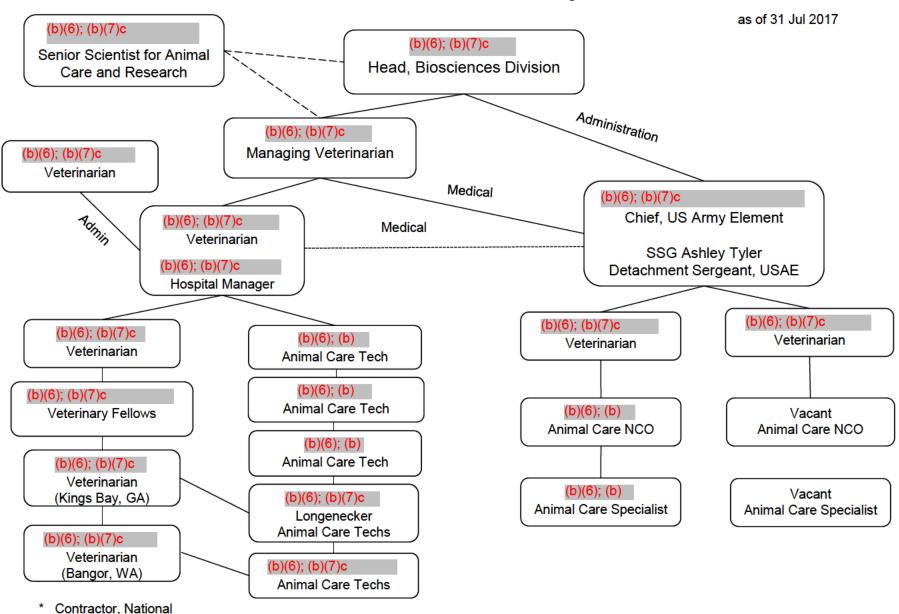
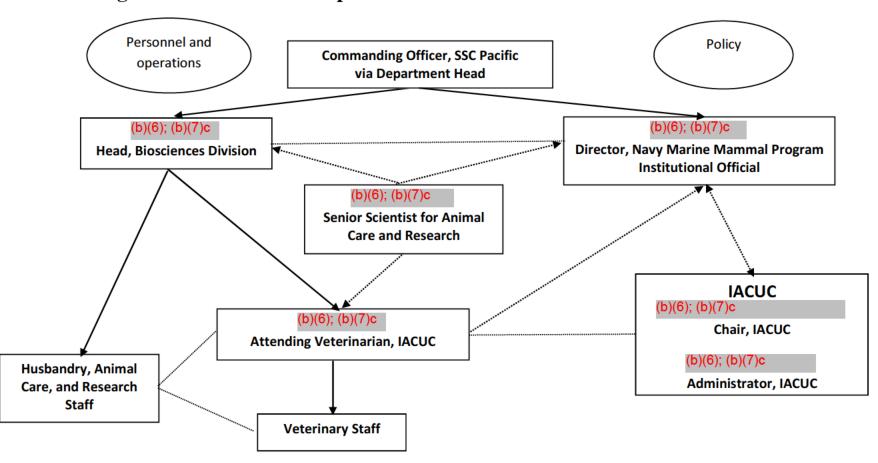
# USN MMP Clinical Veterinary Services



Marine Mammal Foundation

# SSC Pacific Navy Marine Mammal Program Organizational Relationships for the Institutional Animal Care and Use Committee



In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials.

				# Animals	Pain & Distress		-	ecial Co neckma		rations pplicable	e)
Protocol Title	No.	Principal Investigator	Species	Approved	Category (USDA) (1)	SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Pathophysiologic Mechanism of Ammonium Urate Nephrolithiasis in Navy Dolphins ( <i>Tursiops</i> truncatus)	#112-2014	(b)(6); (b)(7)c	Tursiops truncatus	4 Tt	D						
Characterization and Treatment of Metabolic Syndrome and Iron Overload in Navy Bottlenose Dolphins ( <i>Tursiops truncatus</i> )	#113-2015		Tursiops truncatus	42 Tt	С						
Electrophysiology and Behavior of Marine Mammal Hearing and Vision	#114-2015		Tursiops truncatus/ Zalophus californianus	12 Tt 8 Zc	C D						
Metabolic Studies to Formulate Prevention and Treatment Strategies for Ammonium Urate Nephrolithiasis in Navy Dolphins ( <i>Tursiops truncatus</i> )	#115-2015		Tursiops truncatus	24 Tt	D						

Testing an Anesthesia Ventilator for Atlantic Bottlenose Dolphins and	W116 2015	(b)(6); (b)(7)c	Tursiops truncatus/	8 Tt	D			
California Sea Lions Developed Under Navy STTR	#116-2015		Zalophus californianus	8 Zc	D			
Non-invasive Pulmonary Function Testing in California Sea Lions (Zalophus californianus)	#117-2016		Zalophus californianus	9 Zc	С			
Evaluation of Safety and Efficacy of Commensal Probiotics, Lactobacillus salivarius, MMP Strain/L. senioris, Accacia Strain for Maintaining Dolphin (Tursiops truncatus) Health	#118-2016		Tursiops truncatus	20 Tt	С			
Marine Mammal Hearing in Open Ocean Environments	#119-2016		Tursiops truncatus/ Zalophus californianus	12 Tt 8 Zc	C C			
Enhanced Marine Mammal System Performance Through Targeted Neuroplasticity Training	#120-2016		Tursiops truncatus	8 Tt	С			
Behavioral Observation Audiometry to Estimate the Hearing Range in a Mysticete Cetacean, the Humpback Whale (Megaptera novaeangliae)	#121-2016		Tursiops truncatus	50 Tt	С			
Noise-Induced Temporary Threshold Shift (TTS) in Dolphins	#122-2017		Tursiops truncatus	6 Tt	С			

<sup>(1)</sup> Please provide a description / definition of any pain/distress classification used within this Appendix.

<sup>(2)</sup> Survival Surgery(SS) (3) Multiple Survival Surgery(MSS) (4) Food or Fluid Regulation(FFR) (5) Prolonged Restraint(PR) (6)Hazardous Agent Use(HAU)

<sup>(7)</sup> Non-Centralized Housing and/or Procedural Areas (NCA), *i.e.*, use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, *etc*.

# Appendix 3 Summary of Animal Housing and Support Sites

Briefly summarize in the following table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, etc.), the total square footage/meters (or acreage) for animal care and use, and the total square footage/meters (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, HVAC, service corridors, etc. and additional areas to be considered are enumerated in the <u>Guide</u>). If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) each facility is from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an Appendix to provide this information. Provide floor plans of each area as an Appendix. In Section II.B., describe the general types of animal housing facilities available (e.g., conventional, hazard containment, gnotobiotic, barrier, barns, etc.) and other details of the facilities. See <u>Instructions</u>, <u>Appendix 1 - Animal Facility Square Footage/Meters Compilation Form</u> for guidance in calculating the size of your animal care and use program.

	Animal Housing and Support Sites						
Location (building/site /farm name*)	Distance from main facility (campus/site map(s) also may be provided in lieu of this information)	Approx. sq.ft./m (acreage) animal housing	Approx. sq.ft./m (acreage) support/ procedure space	Species housed	Approximate Daily Animal Census by species	Person in charge of site	
Pier 607	See map in Appendix 4	55,800	8,020	Bottlenose dolphins	To be discussed at visit (classified)	Scott Price	
Pier 548	See map in Appendix 4	28,800	2,962	Bottlenose dolphins		66	
Pier 619	See map in Appendix 4	8,100	3820	California sea lion	66	66	
Bldg 606			3200				
Shower trailer (male)			240			"	
Shower trailer (female)			240				
Restroom trailer			215				
Admin/IT Trailer			1500				
Assembly Tent			3200				

Locker Tent		3200			
(b)(3); (b)		16			
restroom					
(male)					
(b)(3); (b)		16			
restroom					
(female)					
Pool watch		132			
trailer					
Pool watch		132			
restroom					
trailer					
(b)(3); (b)		6636			
194 (Vet		2516			
hospital)					
(b)(3); (b)		1788			
(7)(b)		15000			
(3);					
(Bepot)					
(b)(3); (b)		1138			
(7)e					
(b)(3); (b)		1617			
(b)(3); (b)		1053			
(7)e					
(b)(3); (b)		2348			
(b)(3); (b)		2799			
(b)(3);		2539			
(b)(3);		6639			
Tot	als: 92,700	70,966			
Total animal housing	and				
support spa					
support spe	Please specif	fy ft <sup>2</sup> or m <sup>2</sup>			
*Please state name and acros			not goded for a	an fidantiality	

<sup>\*</sup>Please state name and acronyms used for building names, if not coded for confidentiality.















# Enclosure 1 SSC PACIFIC BIOSCIENCES DIVISION CODE 715 ANNUAL OCCUPATIONAL HEALTH RISK ASSESSMENT

Name (Last, First, M.I.):	Rank/Gr	ade:	Date of Bi	Date of Birth:		
Status (circle):	☐ Co	ntractor (list comp	any) 🗆 Un	iversity Affiliate		
Job Title:	Work Ph	one:				
Gender: ☐ Male ☐ Female	□Ini	itial Evaluation	□Annı	ıal		
PART A: OCCUPATIONAL / ENVIRONMENTAL RI Animals/Tissues/Body Fluids(check all that apply)			ncy of Exposu	<u>.</u> r <u>e</u>		
	<u>Daily</u>	1-4 times/ week	1-3 times/ month	Infrequently/ Never		
□ Sea Lions			<u> </u>	<u></u>		
□ Animal Handler		. 🗆				
☐ Handle Tissue or Serum				. 🗀		
<ul><li>Assist/Perform Medical Procedures</li></ul>						
☐ Handle Dead Animals						
☐ Assist/Perform Necropsies				□		
□ Dolphins						
<ul> <li>Animal Handler</li> </ul>						
☐ Handle Tissue or Serum						
<ul> <li>Assist/Perform Medical Procedures</li> </ul>				· 🗖		
☐ Handle Dead Animals						
□ Assist/Perform Necropsies						
□ Work on IACUC approved research protocols						
□ Member of the IACUC						
☐ Student intern or preceptor program				,		
Chemical/Radiation						
I use the following Hazardous Chemicals:						
□ Formaldehyde/Formalin				. 🗖		
☐ Anesthetic Gas (Sevoflurane)						
Others:						
I work with the following Radiation Hazards:	•					
□ Radioactive Isotopes (Auth #:	_) 🗆					
□ X-Rays						

## PART B: PERSONAL PROTECTIVE EQUIPMENT (PPE) USED ☐ Safety Shoes □ Gloves ☐ Respirator (Date of last Fit Test:\_ □ Hard Hat □ Surgical Mask □ Other:\_\_\_\_\_ ☐ Eye Protection □ Face Shield I certify that the above employee has received/will receive proper training and medical surveillance for any hazards to which they are occupationally exposed. Supervisor's Name (PRINT): Phone: Supervisor's Signature: Date: Employee's Signature: Date:

Employee has NO medical restrictions	☐ Employee has medical restrictions
	(Please specify on separate sheet)
PHYSICIAN'S	SIGNATURE
Signature	Date

#### Enclosure 4

## MARINE MAMMAL ZOONOSES FACT SHEET FOR PHYSICIANS AND OTHER HEALTH CARE WORKERS

**Purpose:** The purpose of this document is to provide physicians and other health care workers with information on communicable marine mammal diseases that may be transmissible to people. This information is relevant to patients who work with marine mammals, including people working with the bottlenose dolphins (*Tursiops truncatus*) and California sea lions (*Zalophus californianus*) at the Navy Marine Mammal Program.

**Definition:** Marine mammal zoonoses are communicable diseases that can be transmitted from marine mammals to people.

Marine Mammal Zoonoses: While there are sporadic reports of possible disease transfer from marine mammals to people, the risks of disease transmission from marine mammals to people are not well known. The most commonly reported diseases in humans that have been associated with marine mammals are bacterial infections secondary to bites. The pathogens listed below, however, have been reported to cause disease in both marine mammals and people. It is important to note that this list is similar to pathogens found in many mammals, including household dogs, cats, and rodents.

## Bacteria

Bartonella henselae Brucella spp. Campylobacter spp.

Chlamydophila abortus

Clostridium spp. Coxiella burnetii

Edwardsiella tarda Erysipelothrix

rhusiopathiae Escherichia coli

(toxigenic) *Klebsiella* spp.

Leptospira interrogans

Listeria spp.

Mycobacterium spp.
Mycoplasma spp.
Nocardia spp.
Pasteurella spp.

Pseudomonas aeruginosa

Salmonella spp. Staphylococcus spp. Streptococcus spp.

Vibrio spp.

<u>Fungi</u>

Candida spp. Cryptococcus spp. Lacazia loboi

**Parasites** 

Anisakids

Cryptosporidium parvum

Giardia lamblia Sarcocystis spp. Toxoplasma gondii Trichonella spp.

## <u>Viruses</u>

Influenza virus A and B

Rhabdovirus

Western equine enceph

virus

West Nile virus

## Enclosure 4 (Cont')

Preventing Marine Mammal Zoonoses: Many potential marine mammal zoonoses are similar to those found in household dogs, cats, and rodents. As such, the Centers for Disease Control and Prevention's zoonoses prevention guidelines used for pet owners may be applied to people in contact with marine mammals.

Due to the increased risk of severe disease, the following people should avoid contact with clinical samples (blood, urine, and feces), necropsies, tissues, and high-risk marine mammals:

- Organ transplant recipients
- Children less than 5 years old
- People undergoing chemotherapy treatment
- People with AIDS/HIV
- People with liver cirrhosis
- Pregnant women

Higher-risk marine mammals may include the following:

- Aggressive animals likely to bite
- Sea lion pups less than 6 months old
- Animals with diarrhea
- Animals with respiratory disease
- Animals with acute skin disease of suspected infectious origin

People who may be in contact with Navy marine mammals and/or clinical samples should consult with their physician to determine if they are at risk of severe zoonotic diseases from higher risk marine mammals.

## Resources

If you have specific questions regarding disease transmission from marine mammals to people, we encourage you to contact the Navy Marine Mammal Program directly and/or the California State Public Health Veterinarian.

Stephanie Venn-Watson, DVM, MPH
Veterinary Epidemiologist
Ph: 619.993.1440
<a href="mailto:stephanie.venn-watson@nmmpfoundation.org">stephanie.venn-watson@nmmpfoundation.org</a>
Navy Marine Mammal Program
San Diego, California

Curtis Fritz, DVM, MPVM, PhD
State Public Health Veterinarian
Ph: 916-552-9740
cfritz@cdph.ca.gov
California Department of Public Health
Sacramento, California

## USN MMP IACUC Membership

as of 31 Jul 2017

## 10 Members and 2 Alternate Members

Voting Members	Degrees	Role	Affiliation
(b)(6); (b)(7)c	DVM, MS,	Chair, Alternate	US Army/Bioscience
	MPVM,	Attending Vet	Division code 71510
	DACVPM		
	DVM, 30 yrs	Attending Veterinarian	Bioscience Division code
	MM exp		71510
	Chaplain	Non-Affiliated Member	US Navy/Command
			Submarine Squadron 11
	PhD	Scientific Member	Bioscience Division code
			71500
	31 yrs MM	Member	Bioscience Division code
	experience		71502
	29 yrs MM	Member	Bioscience Division code
	experience		71502
	AA, 10+ yrs	Member	Bioscience Division code
	MM exp		71530
	10+ yrs MM	Member	Bioscience Division code
	experience		71530
	MS	Member	Bioscience Division code
			71530
	10+ yrs MM	Member	Bioscience Division code
	experience		71530
	1	ı	

Alternate Members	Degrees	Role	Affiliation
(b)(6); (b)(7)c	DVM	Alternate Chair	US Army/Bioscience
			Division code 71510
	MS	Alternate Non-Affiliated	US Navy/Naval Health
		Member	Research Center

Non-Voting Positions	Degrees	Role	Affiliation
(b)(6); (b)(7)c	DVM, Dipl	Consultant	US Army/Naval Medical
	ACVPM, Dipl		Center San Diego
	ACLAM		
	10+ yrs Lab	Consultant	Naval Medical Center
	Animal Exp		San Diego
	MS	Administrator	National Marine
			Mammal Foundation



Name of Facility

## Appendix 7



## US NAVY MARINE MAMMAL PROGRAM DOD ANIMAL USE PROTOCOL COVER SHEET

	a. Marine Mammal Facility: U.S. Navy Marine Mammal Pr b. P.I. Facility: U.S. Navy Marine Mammal Program, SSC	
II. III.	Proposal Number: Title:	
IV.	Principal Investigator (and Co-Investigator)	
	Printed Name (First, MI, Last):	
	Title: Phone: E-mail:	Division: Fax:
	Signature	Date (YYYYMMDD)
V.	Scientific / Division Review: (b)(6); (b)(7)c , D.V.M., Ph.D.,	Dipl. ACZM
	Title: Senior Scientist for Animal Care and Research Phone: 619-553-1374 E-mail: (b)(6); (b)(7)c	Division: SSC Pacific Biosciences Division Fax: 619-553-2678
	Signature	Date (YYYYMMDD)
VI.	Statistical Review: (b)(6); (b)(7)c , Ph.D.	
	Title: Research Scientist Phone: 619-767-4335 E-mail: (b)(6); (b)(7)c	Division: SSC Pacific Biosciences Division Fax: 619-553-5068
	Signature	Date (YYYYMMDD)
VII.	Attending Veterinarian Review: (b)(6); (b)(7)c D.V.M.	
	Title: Managing Veterinarian Phone: 619-553-2863 E-mail: (b)(6); (b)(7)c	Division: SSC Pacific Biosciences Division Fax: 619-553-5068
	Signature	Date (YYYYMMDD)

NOTE: ALL SIGNATURES MUST BE RECEIVED BEFORE ROUTING PROTOCOL THROUGH IACUC

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## U.S. NAVY MARINE MAMMAL PROGRAM DOD ANIMAL USE PROTOCOL

PRIN	TOCOL TITLE: CIPAL INVESTIGATOR(S): NVESTIGATOR(S):
I.	NON-TECHNICAL SYNOPSIS:
II.	BACKGROUND
	II.2. <u>Literature Search for Duplication:</u> This search must be performed to prevent unnecessary duplication of previous experiments. A search of the Federal Research in Progress (FEDRIP) or National Institutes of Health (NIH) Research Portfolio Online Reporting Tools (RePORT) is required.
	II.2.1. Literature Sources Searched: (Either FEDRIP or RePort are required)
	<ul> <li>☐ Federal Research in Progress (FEDRIP)</li> <li>☐ Research Portfolio Online Reporting Tools (RePORT)</li> <li>☐ Others (please specify):         <ul> <li>(e.g., NMMP Biosciences Division EndNote Library (21,800 entries))</li> </ul> </li> </ul>
	II.2.2. Date of Search: II.2.3. Period of Search: II.2.4. Key Words of Search:
	II.2.5. Results of Search:
	To address the components of this research proposal, literature searches were conducted for each area. Relevant results are as follows:
III.	OBJECTIVE / HYPOTHESIS:
IV.	MILITARY RELEVANCE:
V.	MATERIALS AND METHODS
	V.1. Experimental Design and General Procedures:
	V.2. Data Analysis: Please check all statistical test(s) planned and/or strategies intended to evaluate the data:
	Type of Study ☐ Prospective study with animal samples (i.e., non-clinical diagnostic tests)
	Statistical Analyses  □ Descriptive statistics / frequencies □ Other (please specify):

Describe statistical approach:
Please check all means used to determine the minimum number of study animals:
□ Availability limitation of MMP animals
V.3. Laboratory Animals Required and Justification
V.3.1. Non-animal Alternatives Considered
V.3.2. Animal Model and Species Justification: Provide a scientific justification for the choice of animal model(s). What physiological and morphological characteristics does this animal possess that make it the best possible model? If less sentient (invertebrate versus vertebrate) animal models were considered but not chosen, explain why.
(See V.3.1 above)
V.3.3. Laboratory Animals
V.3.3.1. Genus and Species (please check all that apply)
<ul> <li>□ Zalophus californianus (california sea lion)</li> <li>□ Tursiops truncatus (bottlenose dolphin)</li> </ul>
V.3.3.2. Strain / Stock:
Navy MMP animals will be participating in the proposed research. Specific animals to be used in the protocol are at the discretion of Dr. Mark Xitco, Division Head, Biosciences Division, SSC-SD Code 71500.
V.3.3.3.Source / Vendor:
Animals at the Navy MMP will participate in the proposed research. The MMP is AAALAC International accredited and submits annual animal care and use reports to the USDA/APHIS, AAALAC International, and the DOD as directed.
V.3.3.4 Age:
☐ There are no age requirements for this study.
V.3.3.5. Weight:
☐ There are no weight requirements for this study.
V.3.3.6. Sex:
☐ There are no sex requirements for this study.
V.3.3.7. Special Considerations (e.g., health status, training behavior):
☐ There are no special considerations for this study

Proposed animals were selected based on their potential availability and training. The dolphins are already trained to beach and transport to an indoor pool facility. The sea lions are already trained to transport to the quiet testing room. Behavioral hearing tests require subjects to be trained in the specific hearing test behaviors (see V.1.)

V.3.4. Number of Animals Required (by Species): **The number of animals stated here must correspond exactly to that described in Section V.1.** If, during completion of the protocol, additional animals are needed owing to technical or unavoidable circumstances, or to exploit a serendipitous finding, follow IACUC procedures for requesting approval of additional animals. Be certain to include animals necessary for controls or technique development, and so forth.

Zalophus californianus (California sea lion) #
Tursiops truncatus (Bottlenose dolphin) #

V.3.5. Refinement, Reduction, Replacement (3 Rs): Investigators are required to consider the 3 Rs when preparing an animal use research protocol. In the paragraphs below, describe all provisions in this protocol that refine, reduce, or replace the use of animals. Discuss what provisions were considered and why they were not chosen. If N/A is used, explain why.

## V.3.5.1. Refinement

Please check all measures or procedures to be taken to eliminate pain or distress in the animal(s) or to enhance animal well-being:

Use of analgesia to decrease pain or distress
Use of remote telemetry to decrease the distress of restrain
Use of adjusted early end points
Other (please specify)

The Navy Marine Mammal Program has Standard Operating Procedures (SOPs) for the beaching and transportation of marine mammals and for working animals in open water environments. These SOPs will be employed when applicable for this project. There were no additional refinement alternatives that would allow the scientific objectives to be met and were considered but not adopted.

## V.3.5.2. Reduction

Please check all measures or procedures to be taken to reduce the number of animals used:

- □ Shared historical control groups
   □ Use of archived samples / data
   □ Preliminary screening in non-animal systems
   □ Innovative statistical package
   □ Other (please specify):
- ☐ There were no additional replacement alternatives that would allow me to meet my scientific objectives and were considered but not adopted. Note: If this box is not checked, explain why additional replacement alternatives were not considered.

## V.3.5.3. Replacement

Please check all measures or procedures to be taken that eliminate the use of animals:

Use of non-animal models
Use of less sentient animal species
Other replacements (please specify):

☐ There are no sex requirements for this study. There were no additional replacement alternatives that would allow me to meet my scientific objectives and were considered but not adopted. Note: If this box is not checked, explain why additional replacement alternatives were not considered.

<u>V.4. Technical Methods</u>: This information must be presented in sufficient detail, documented or referenced, so that the IACUC can adequately review the procedure, obtain a clear understanding of what is to be done and how the animals will be handled, and make a reasonable determination as to whether this proposed use of laboratory animals is in compliance with DOD regulations, guidelines, and Federal law.

V.4.1. Pain / Distress Assessment: The law defines a painful procedure as one that would "reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied; that is, pain in excess of that caused by injections or other minor procedures." If a procedure may involve pain or distress, even if relieved by anesthetics or analgesics, the P.I. must consult with the attending veterinarian.

V.4.1.1. APHIS Form 7023 Information: (see your attending veterinarian for assistance). The protocol must contain an estimate of the number of animals that will be counted in columns C, D, and E of the APHIS Form 7023, Annual Report of Research Facility. Columns C, D, and E represent specific pain categories. The animal should be listed in the column corresponding to the most painful or distressful procedure experienced by the animal. It is possible for one protocol to have animals listed in several columns. For instance, control animals may be placed in Column C while experimental animals may be placed in Column D, depending upon the nature of the protocol. Reflect use of more than one species of animal in a duplicate table. The total numbers reflected in these three columns will add up to the number of animals requested for the entire protocol in paragraph V.3.4.

## V 4.1.1.1. Number of Animals

## V. 4.1.1.1. Column C: (animal #)

Examples of research procedures/manipulations that would require an animal to be placed in Column C are studies involving not more than slight or momentary pain and/or distress in a human being to which that procedure is applied.

## V. 4.1.1.1.2. Column D: (animal #)

Examples of research procedures/manipulations that would require an animal to be placed in Column D are procedures where anesthesia or analgesia will be administered to avoid or effectively relieve pain or distress. General anesthesia given for surgical procedures, and the use of analgesia or anti-inflammatory agents, are examples of this category.

## V.4.1.1.3. Column E: (animal #)

Examples of research procedures/manipulations that would require an animal to be placed in Column E are procedures in which alleviation of pain or distress are contraindicated for a scientifically justifiable reason such as the experimental results are likely to be confounded if drugs relieving pain or distress were administered. Detailed justification for putting animals into this category is required below in paragraph V.4.1.4.

#### V.4.1.2. Pain Relief / Prevention

V.4.1.2.1. Anesthesia / Analgesia / Tranquilization: Describe the methods or strategies planned to effectively relieve or prevent pain or distress if the study will cause more than slight momentary pain or distress.

Г			
- 1			
- 1			
L			

	☐ This study will not caus	se more than slight mom	entary pain or distres	s to animals.
	Note: If this box is not chec please provide agent infor		nimal is listed under (	Columns D or E),
	Anesthesia / Analgesia / Tranquilization Agent	When Given (e.g., pre- emptive or post- procedural)	Dosage	Frequency
proc obse	1.2.2. Pre- and Post-procedu edural care, including provisi ervations (information concer 3.1 and V.4.3.3).	ons for post-procedural	observations and free	quency of
	Pre- and Post-procedural Provisions	Type (s)	Frequency	Duration
	Observational criteria utilized		are experiencing pair	n or distress:
	Location of post-procedural o	eare:		
V.4.	1.2.3. Paralytics: ☐ Paralyti	c agents will not be used	I in this study.	
V.4.1.3.	Literature Search for Alterna	tives to Painful or Distres	ssful Procedures:	
	I/A (Animals will not experien Dlumn C of APHIS Form 7023			
V.4.	1.3.1. Source(s) Searched (e	.g., AGRICOLA, MEDLII	NE, BIOSIS, Altweb):	
V.4.	1.3.2. Date of Search:			
V.4.	1.3.3. Period of Search:			
V.4.	1.3.4. Key Words of Search (	e.g., pain, surgery, alter	natives, LD 50):	
narra the p The	1.3.5. Results of Search: The ative description of the metho painful procedure were not avalternatives literature search the pain or distress is alleviated.	ods and sources that he/ vailable. Discuss alternat MUST be performed ev	she used to determin lives that were considen when animals are	e that alternatives to lered but not chosen placed in Column D
V.4.	1.4. Unalleviated Painful / Dis	stressful Procedure Justi	fication:	
	nimals will not be involved in	procedures that cause	more than slight or m	omentary pain or

distress that is not alleviated through the effective use of anesthetics or analgesics.

Note: If this box is not checked, studies involving unalleviated pain must be justified on a scientific basis in writing by the P.I. (i.e., any animals in this protocol listed under Column E).

V.4.2. Prolonged Restraint: Describe and justify in detail any prolonged restraint greater than 12 hours for nonhuman primates or in accordance with IACUC policy for other species. Examples of restraint methods are primate chairs, restraint boards, metabolism cages, and so forth. This section is not intended for short-term actions such as rabbit restraint for bleeding, and so forth.

☐ This study will not involve prolonged restraint.  Note: If this box is not checked, please provide relevant restraint information below.					
Restraint Method	Habituation / Training to Animal Restraint Device				

Provide justification for each restraint method to be used.

V.4.3. Surgery: Major survival operative procedures on non-rodent species will be conducted only in dedicated facilities intended for that purpose, and operated and maintained under aseptic conditions. A major operative procedure is defined as a procedure that penetrates and exposes a body cavity, or causes substantial or permanent impairment of physical or physiological function.

	l I his	study	will no	t invo	ive su	rgical	procedi	ures.
--	---------	-------	---------	--------	--------	--------	---------	-------

V.4.3.1. Pre-Surgical Provisions:

V.4.3.2. Procedure:

V.4.3.3. Post-Surgical Provisions:

V.4.3.4. Location of Surgery:

V.4.3.5. Surgeon:

V.4.3.6. Multiple Major Survival Operative Procedures:

☐ This study will not involve multiple major survival operative procedures. If checked, please SKIP to Section V.4.4.

V.4.3.6.1. Procedures: NA

V.4.3.6.2. Scientific Justification: NA

V.4.4. Animal Manipulations: Describe any injections, sampling procedures, or other manipulations of the animals necessary for the study. A reference or SOP may be furnished to the IACUC to document a particular procedure in lieu of a detailed description.

## V.4.4.1. Injections

Agent	Route	Dosage	Frequency	Volume Injected	Needle Size	Anatomic Injection Site	
						injection one	
		•	•	•	•	•	
V.4.4.2. Bios	samples:						
☐ This stud	dy will not inve	olve biosamp	oles.				
V.4.4.3. Adju	ıvants:						
☐ This stud	dy will not inv	olve adjuvan	ts.				
V.4.4.4. Mor	oclonal Antib	ody (MAbs)	Production:				
☐ This stu	☐ This study will not involve <i>in vivo</i> monoclonal antibodies (MAbs).						
V.4.4.5. Animal Identification:							
physical an	Animals at the MMP are recognized by animal handlers and veterinarians based upon unique physical and behavioral characteristics. DNA from each animal is currently archived at Portland State University.						
V.4.4.6. Beh	7.4.4.6. Behavioral Studies:						
V.4.4.7. Oth	/.4.4.7. Other Procedures:						
V.4.4.8. Tiss	ue Sharing: N	No tissues wi	ll be shared.				
			study endpoin early euthana	t for the animals (fo	r example, reco	very and returr	
Indicate	which study	endpoint is e	xpected:				
□ Reco	very						
			mining when the stion answere	ne animal experimer ed?):	ntation phase wi	II be stopped	
Define s	pecific criteria	a that will be	used to determ	nine a study endpoir	nt for animal hea	alth purposes:	
□ Clinic	al illness asse	essed by atte	ending veterina	rian			
			r removal fror Iammal Progr	n the study, subjec	cts will continu	e their roles	

### V.4.6. Euthanasia:

☐ This study will not involve animal euthanasia or death without early euthanasia.

The Animal Welfare Act defines euthanasia as "human destruction of an animal by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death." The current American Veterinary Medical Association (AVMA) guidelines for euthanasia must be followed. Exceptions to the AVMA guidelines will be considered on a case-by-case basis. If requested, the attending veterinarian will assist in selecting the best method for euthanasia.

## V.5. Veterinary Care

## V.5.1. Husbandry Considerations:

The Navy Marine Mammal Program (MMP) provides animals with housing and living conditions that are appropriate to their species and contribute to their health and comfort. The MMP is AAALAC accredited and submits annual reports regarding their care and use of animals to the DOD, USDA/APHIS, and AAALAC. Federal regulations (e.g., the Animal Welfare Act and the Marine Mammal Protection Act) related to marine mammal husbandry are strictly followed. Dolphins and sea lions are housed in open-ocean, netted enclosures in San Diego Bay. Routine animal observations, including assessments of appetite, appearance, activity, animal interactions, and people interactions, are conducted daily by animal trainers and logged into a central electronic database; abnormalities are reported directly to attending veterinarians. A variety of high-quality frozen-thawed fish (and water for sea lions) are provided to animals via multiple daily feedings by trainers; amounts of food broken out vs. eaten are tracked, by lot number, for each animal via handheld electronic data systems. Ocean pen platforms are cleaned daily, and nets are routinely monitored and changed when needed.

## V.5.1.1. Study Room:

	Where will the experimental procedure(s) be conducted? Check all that apply.
	<ul> <li>□ Normal animal housing – in water</li> <li>□ Normal animal housing – out of water</li> <li>□ Other (please specify):</li> </ul>
	If the procedure is being conducted outside normal animal housing (in water), will the animal be housed in any of these spaces for more than 12 hours?
	□ Yes □ No
	. Special Husbandry Provisions: Examples include micro-isolators, metabolic cages, food and estriction.
	☐ This study will involve no special husbandry provisions.
V.5.1.3	. Exceptions:
	☐ This study will involve no deviations / exceptions to <i>The Guide for the Care and Use of Laboratory Animals</i> , the Animal Welfare Act regulations, and IACUC policy that have an impact on animal housing space, feeding, and sanitation.

### V.5.2. Veterinary Medical Care

## V.5.2.1. Routine Veterinary Medical Care:

MMP animals undergo routine physical examinations by MMP veterinarians (annual for non-Fleet animals, semi-annual for Fleet animals). Medical checks are conducted and recorded by trained animal handlers on a daily basis; abnormalities are reported to attending veterinarians for follow-up clinical examinations. If the animal becomes ill or debilitated during the study and requires evaluation, the attending or on-call veterinarian will respond and provide medical care as needed. In the event of debilitating illness or an adverse reaction during the study, alternative early endpoints will be assessed and veterinary medical treatment will be provided. Criteria for health evaluation while the animals are on the study will include the following:

- Abnormal appetite
- Abnormal appearance
- Abnormal activity
- Abnormal animal interactions
- Abnormal people interactions
- Abnormal complete blood work and serum chemistries, as interpreted by attending veterinarian
- Abnormal weight loss
- Other clinical signs

## V.5.2.2. Emergency Veterinary Medical Care:

On-call veterinarians and emergency veterinary medical care is available for MMP animals 24 hours a day, 7 days a week, including holidays. Emergency medical supplies are staged in appropriate areas to ensure rapid response to emergency animal health issues.

## V.5.3. Environmental Enrichment

## V.5.3.1. Enrichment Strategy: NA

Navy MMP animals live in open ocean enclosures that provide natural environmental enrichment. Additionally, MMP animals are most often housed with each other within the same pens and have visible and acoustic access to many animals within the MMP population. Animal trainers interact with animals during training and feeding sessions multiple times per day, 7 days per week. Physical objects (e.g., rub ropes) approved by the MMP Animal Safety Committee are also used for MMP animal environmental enrichment.

## V.5.3.2. Enrichment Restriction:

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_	THIS STUUT	/ 111701763		. 1630160013

## VI. STUDY PERSONNEL QUALIFICATIONS AND TRAINING

Note: Include personnel performing observations, procedures, and/or manipulations described in the protocol.

Name	Procedure(s)	Qualifications	Training / Species

## VII. BIOHAZARD / SAFETY

List potential biohazards associated with the chosen animal model and this research proposal (for example, viral agents, toxins, radioisotopes, oncogenic viruses, and chemical carcinogens):

The SSC Pacific Safety and Environmental Office oversees the MMP's biohazard and safety program, including formal training of personnel; ordering and disposal of hazardous materials; tracking of on-site HAZMAT; and provision of Material Safety and Data Sheets (MSDS) (POC: Ms. Mary Ann Flanagan).

## VIII. ENCLOSURES

Enclosures such as IACUC policies on adjuvants, monoclonal antibody production, tissue sharing, food and/or water restriction, prolonged restraint, pathology addenda, and pain assessment criteria may be included at the discretion of the PI unless directed by the IACUC.

VIII.1. References:

## **ASSURANCES**

The law specifically requires several written assurances from the Principal Investigator. Please read and sign the assurances as indicated.

As the Principal Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

- A. Animal Use: The animals authorized for use in the protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC prior to its implementation.
- B. Duplication of Effort: I have made every effort to ensure that this protocol is not an unnecessary duplication of previous experiments.
- C. Statistical Assurance: I assure that I have consulted with a qualified individual who evaluated the experimental design with respect to the statistical analysis, and that the minimum number of animal needed for scientific validity will be used.
- D. Biohazard / Safety: I have taken into consideration and made the proper coordinations regarding all applicable rules and regulations concerning radiation protections, biosafety, recombinant issues, and so forth, in the preparation of this protocol.
- E. Training: I verify that the personnel performing the animal procedures/manipulations/observations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures/manipulations.
- F. Responsibility: I acknowledge the inherent moral, ethical, and administrative obligations associated with the performance of this animas use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to conduct this study in the spirit of the fourth "R", namely "Responsibility," which the DOD has embraced for implementing animal use alternatives where feasible and conducting humane and lawful research.
- G. Scientific Review: This proposed animal use protocol has received appropriate scientific peer review and is consistent with good scientific research practice.
- H. Painful Procedures:

I am conducting biomedical experiments, which may potentially cause more than momentary or slight pain or distress to animals. This potential pain and/or distress WILL or WILL NOT (circle one or both, if applicable) be relieved with the use of anesthetics, analgesics, and/or tranquilizers. I have considered alternatives to such procedures; however, I have determined that alternative procedures are not available to accomplish the objectives of this proposed experiment.

Not Applicable (circle if appropriate):	The biomedical experiments will not cause pain or distress
Print Name	
Signature	Date (YYYYMMDD)

## **MEMORANDUM**

From:

Director, Navy Marine Mammal Program, Code 71005

To:

Distribution

Subj:

MINUTES OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

MEETING, 31 MAR 2016

Encl:

(1) IACUC Sign-in Sheet

(2) IACUC Training Sign-in Sheet

(3) DoD Semiannual Program Review / Facility Inspection Checklist

- 1. This document reports the minutes of the meeting of the Space and Naval Warfare Systems Center Pacific (SSC Pacific) Institutional Animal Care and Use Committee (IACUC) convened at 1230 hours, 31 March 2016. The IACUC met to review active research protocols, provide refresher training on Animal Care and Use Program Research Protocol Reviews, and conduct a semiannual program review and facilities inspection.
- 2. A sign-in sheet, enclosure (1), was circulated to record attendance. IACUC members present were:

```
CPT Virginia White, Code 7151, Chair
(b)(6); (b)(7)c Code 7151, Attending Veterinarian Member
(b)(6); (b)(7)c
                       Navy Medical Center, San Diego, Non-Affiliate Member
                    Navy Medical Center, San Diego, Alternate Non-Affiliate Member
(b)(6); (b)(7)c
(b)(6): (b)(7)c
                    Member
(b)(6); (b)(7)c
                     Code 71502, Member
(b)(6); (b)(7)c
                       Alternate Chair
               Code /1500, Scientific Member
(b)(6); (b)(7)c
(b)(6); (b)(7)c
                        IACUC Administrator
```

The IACUC Chair (Chair) called the meeting to order at 1245 hours, welcomed the IACUC members and reviewed the agenda for the meeting.

## Old Business

The Administrator distributed a copy of the DoD Semiannual Program Review/Facility Inspection Checklist and the DoD Semiannual Program Review/Facility Inspection Signature Sheet/Minority Opinions Form from the 22 October 2015 meeting for review and signature.

The Administrator distributed copies of the Active Protocols and Protocol Status Report to the IACUC members. The Chair reported that the approval of Protocol #115-2015, submitted by (b)(6); (b)(7)c (b)(6); (b) was approved via designated review. The Chair also reported that Protocol #117-2016 was approved by designated review and was submitted to the Navy Bureau of Medicine and Surgery (BUMED) for their concurrence of approval.

The Chair reported that the Biosciences Division, Information Technology (IT) reported that it would be cost prohibitive to run computer lines between SSC Pacific and Naval Medical Center, San Diego, and that they recommended that 'read-only' versions of the IACUC files be stored on a server at Naval Medical Center, San Diego, for the Non-affiliate members. (b)(6); (b)(7)c reported that he has

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contacted the IT group at Naval Medical Center, San Diego about housing the IACUC files on a server at the Center, but has not received a response from them yet.

The Chair reported that the Biosciences Division is drafting a memorandum for the Commanding Officer's (CO) signature to have (b)(6); (b)(7)c remain the IACUC Institutional Official (IO). Once the CO signs the IO memorandum, (b)(6); (b)(7)c will replace (b)(6); as the Scientific Member on the IACUC.

#### 4. New Business

## IACUC Membership

The Chair reported that Mr. Scott Price and Ms. Jennie Shield would be appointed to the IACUC after the CO memorandum regarding the IO is signed.

#### Protocol #116-2015

The Chair informed the IACUC that there was a request for a Full Committee review of protocol #116-2015 (Testing an Anesthesia Ventilator for Atlantic Bottle Nose Dolphins and California Sea Lions developed under STTR (Small Business Technology Transfer), submitted by (b)(6); (b) (b)(6); (b)(7)c was unable to attend the IACUC meeting, however, the Chair led a discussion on the protocol. (b)(6); (b) expressed his concerns about anesthetizing healthy noncompromised animals and questioned why the ventilator testing couldn't be performed during times when an animal was undergoing a medical procedure. (b)(6); (b)(7)c expressed the need to use non-compromised animals to ensure a good scientific study is performed. (b)(6); voiced his concern that the current ventilator is getting old and the company that developed it no longer exists and there was a need to have a new ventilator. (b)(6); (b) discussed how the current ventilator did a good job mimicking marine mammal breathing, however, procedures taking more then two hours could result in perfusion issues and potential acidosis. He stated that in part, the protocol and ventilator were developed to address procedures that take longer then two hours. (b)(6); (b) added that the ventilator and procedures are a shift in approach for anesthetizing marine mammals.

(b)(6); (b) questioned whether there were procedures that were simple (e.g., teeth cleaning) during which the ventilator could be tested. (b)(6); (b) responded that there were currently some procedures that are performed on non-compromised animals, however, there was a need to test on non-compromised animals to get accurate baseline data.

(b)(6); (b)(7)c questioned whether the ventilator was being tested on other species prior to being tested on marine mammals. (b)(6); (b) informed the IACUC that the ventilator will be tested on pigs and hotses at the University of Missouri prior to testing on marine mammals and that the investigator will get that information from these trials prior to testing on marine mammals. (b)(6); (b) recommended that the IACUC take a similar approach that was taken with the stem (cell protocol where the IACUC reviews the information from the pig and horse trials prior to allowing testing on marine mammals. Additionally, the investigators would be required to report back to the IACUC after each marine mammal trial prior to moving forward with another animal subject. The Chair informed the IACUC that the protocol plans to take such an approach. (b)(6); (b)(7)c expressed the need to have an option to modify the protocol if necessary, after the results from the University of Missouri are received and reviewed.

(b)(6); (b)(7)c questioned whether a CRADA (Cooperative Research and Development Agreement) is needed with the University of Missouri to ensure that the IACUC and the Principal

Subj:

MINUTES OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE MEETING. 31 MAR 2016

Investigator get the information on the pig and horse trials. (b)(6); (b) recommended that the IACUC ask (b)(6); (b) about what assurances he had that he would receive the University of Missouri study results and how those results would be reviewed.

(b)(6); (b)(7)c stated that it was important when testing on marine mammals that procedures are consistent. (b)(6); (b) expressed similar concerns and that the induction and maintenance procedures be consistent for each animal species (dolphins and sea lions).

(b)(6); (b)(7)c expressed that it would be beneficial to obtain a copy of the University of Missouri's protocol for pigs and horses.

The Administrator requested that all IACUC members send him questions they had regarding the protocol. The Administrator agreed to provide those questions to (b)(6); (b) and to arrange a full committee meeting with (b)(6); (b) to discuss the protocol, (7)

Semiannual Facilities Inspection Field Notes Form

The Administrator provided the IACUC members with a copy of the Semiannual Facilities Inspection Field Notes form that was developed. The form was developed to help facilitate the notation of deficiencies during facilities inspections.

(b)(6); (b) mentioned that it would be beneficial for new members and those not familiar with the SSC Pacific facilities to have terminology or guidance to aid them during their inspections. (b)(6); (b) concurred with the need to get some additional background on the SSC Pacific facilities to aid in her inspections. The Chair stated that she has a presentation on facilities inspections at SSC Pacific that the Army provides to new personnel and agreed to provide the presentation to the IACUC members.

(b)(6); (b) expressed his desire to have a copy of the DoD Semiannual Program
Review/Facilities Inspection Checklist for guidance during his inspections in addition to the
Semiannual Facilities Inspection Field Notes form. (b)(6); (b)(7)c recommended that
the DoD Semiannual Program Review/Facilities Inspection Checklist be modified to be more
specific to the SSC Pacific facilities. It was agreed that the Administrator would work with the
Chair to create a modified version of the DoD Semiannual Program Review/Facilities Inspection
Checklist that better reflects unique issues at the SSC Pacific facilities.

#### 5. Protocol Review

The Chair reported on the updates to each of the Active Protocols. (b)(6); (b) reported that there were ongoing discussions regarding protocol #111-2014 and that the protocol will probably be reopened this year. The Chair questioned whether there were any results for protocol #112-2014. (b)(6); (b) reported that the data were still being analyzed. (b)(6); (b) questioned whether Principal Investigators were present during protocol reviews at Naval Medical Center, San Diego. MAJ Johnson reported that they are present sometimes, especially with pilot investigations.

## 6. Training

The Chair provided training titled "Animal Care and Use Program Research Protocol Reviews." There was no discussion.

Subj:

MINUTES OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE MEETING, 31 MAR 2016

# 7. Animal Care and Use Program Review

The Chair guided the IACUC through a Program Review for SSC Pacific. (b)(6); (b) agreed to update the VetLab personnel listing. The Chair informed the IACUC that there will be changes to the Occupational Health program and that she would follow-up with Naval Medical Center, San Diego personnel to make sure that all needed information is obtained. (b)(6); (b) informed the IACUC that if euthanasia is needed, the VetLab SOP for euthanasia will be employed, with the animal's welfare as the priority. Per the SOP, the Senior Scientist, Bioscience Division management, and IACUC will be consulted if the animal's welfare could be compromised. In emergency situations, the decision to euthanize an animal remains with the Attending Veterinarian.

# 8. Facilities Inspection

The IACUC reviewed the Semiannual Inspection Checklist and Action Items from the 22 OCT 2015 inspection. The IACUC then broke into teams and performed the SSC Pacific Bayside and Naval Mine and Anti-submarine Warfare Command (NMAWC) semiannual facilities inspection.

# 9. The meeting was adjourned.

All committee members reviewed and approved these minutes via electronic mail.

(b)(6); (b)(7)c		6/3/	1 L			
(b)(6); (b)(7)c	Chair	Da	ite			
	(b)(6); (b)(7)					
Approved by:_			(	o·1.	16	
	(b)(6); (b) (7)	Director, Nav	y Marine Mar	nmal Pro	gram, Cod	e 71005, Date
Distribution:						
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71502 (w/o enc.	1)					
Committee Mer	nbers (w/o en	c1)				

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Written by: (b)(6); (b)(7)c 71500, x0887 Typed by: (b)(6); (b) 715, x35252, 24 May 16 (7) (b)(6); (b)(7)c

Reviewed by: \_

# **IACUC MEETING SIGN-IN SHEET**

Date: 31 MAR 2016

Name	Signature
(b)(6); (b)(7)c	

# IACUC MEETING SIGN-IN SHEET

Date: 31 MAR 2016

	Name	Signature	
(b)(6); (b)(7)c			

#### **MEMORANDUM**

From: Head, Biosciences Division, Code 715

To: Distribution

Subj: MINUTES OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

MEETING, 6 OCT 2016

Encl: (1) IACUC Sign-in Sheet

(2) IACUC Training Sign-in Sheet

- (3) DoD Semiannual Program Review / Facility Inspection Checklist
- 1. This document reports the minutes of the meeting of the Space and Naval Warfare Systems Center Pacific (SSC Pacific) Institutional Animal Care and Use Committee (IACUC) convened at 1300 hours, 6 October 2016. The IACUC met to review active research protocols, provide refresher training on Ethics of Animal Use in Research, and conduct a semiannual program review and facilities inspection.
- 2. A sign-in sheet, enclosure (1), was circulated to record attendance. IACUC members present were:

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(b)(6); (b)(7)c
                        Code 7151, Alternate Chair
(b)(6); (b)(7)c
                 Code 7151, Attending Veterinarian Member
(b)(6); (b)(7)c
                     Navy Medical Center, San Diego, Alternate Non- Affiliate
Member
(b)(6); (b)(7)c
                Code 71502, Member
(b)(6); (b)(7)c
                         Code 71500, Scientific Member
(b)(6); (b)(7)c
                     Code 71502, Member
(b)(6); (b)(7)c
                   Code 71500. Member
(b)(6); (b)(7)c
                     Code 71502, Member
(b)(6); (b)(7)c
                        Code 7151
(b)(6); (b)(7)c
                  Navy Medical Center, San Diego
(b)(6); (b)(7)c
                        IACUC Administrator
```

The IACUC Alternate Chair (Chair) called the meeting to order at 1310 hours, welcomed the IACUC members and reviewed the agenda for the meeting.

## 3. Old Business

The Administrator distributed a copy of the DoD Semiannual Program Review/Facility Inspection Checklist, and the DoD Semiannual Program Review/Facility Inspection Signature Sheet/Minority Opinions Form from the 31 March 2016 meeting, for review and signature.

The Administrator distributed a new version of the Semiannual Facilities Inspection Field Notes to the IACUC members. He asked the IACUC members to use the new version of the

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Field Notes during their inspection and report back to him if the members wanted changes made to the document.

The Chair asked that IACUC members be very specific about identifying the locations of deficiencies so they can be found by those assigned to addressing the deficiencies. (b)(6); (b) recommended providing IACUC members with copies of the Bay Side and NMAWC base maps along with a copy of the Pen Maps for IACUC members to use during their inspections. (b)(6); (b) informed the Administrator that Scott Price can be contacted for the Pen Maps. The Administrator will obtain copies of the three maps and make copies available for the next inspection.

The Administrator distributed copies of the Active Protocols and Protocol Status Report to the IACUC members. The Chair reported on the approval of Protocol #117-2015 (NRD-1024) submitted by (b)(6); (b) and Protocol #118-2016 (NRD-1049) by (b)(6); (b)(7)c which were approved via designated review.

# 4. New Business

# **IACUC Members Status**

The Chair reported that (b)(6); (b)(7)c will be the new SSC Pacific IACUC Chair and Alternate Attending Veterinarian at the end of October, when (b)(6); (b)(7)c retires. The Chair also reported that (b)(6); (b)(7)c will be the IACUC's new Non-Affiliate Member.

# **Approved Protocols and Protocol Amendments**

The Chair reported that Protocol #116-2015 (NRD-1056) by Dr. Ridgway was approved by full committee review and that Amendment 1 to Protocol #114-2015 (NRD-969) by Dr. Finneran, which was approved via designated review.

# Principal Investigator (PI) IACUC Training

The Administrator reported that under the Animal Welfare Act (AWA) and Public Health Service (PHS), Principal Investigators (PI) must have IACUC training. While some PI have taken IACUC training in the past, most have taken it at institutions other than SSC Pacific, and most have not had training for a number of years. The Administrator reported that he would develop a PI IACUC training curriculum and provide it to the IACUC members for their review. Once the curriculum is completed, it will be distributed to the PI and they will complete the training at their convenience.

# **Protocol Template Updates**

The Administrator reported to the IACUC that there were three sections of the Protocol Template that were updated. The first was the change in the required literature databases that PI need to search when generating a protocol. The Computer Retrieval of Information of Scientific Projects (CRISP) has been replaced by Research Portfolio Online Reporting Tools (RePORT). PI must search RePORT or the Federal Research in Progress (FEDRIP) databases when generating their protocols.

The Administrator reported that the new SSC Pacific HAZMAT contact is (b)(6); (b)(7)c (b)(6); (b) and the Protocol Template has been updated to reflect that change.

Subj: MINUTES OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE MEETING, 6 OCT 2016

The final update to the Protocol Template was the addition of the statement 'Not Applicable (circle if appropriate): The biomedical experiments will not cause pain or distress' to the Assurance Page of the Protocol Template. This was added to address those protocols that will not result in potential pain or distress and there will be no anesthetics, analgesics and/or tranquilizers used on the animal subjects.

## 5. Protocol Review

The Administrator led the IACUC on the review of all the Active Protocols. (b)(6); (b)(7)c (b)(6); (b) provided additional details on Protocols #110-2014 (NRD-912) and #114-2015 (NRD-969) by (b)(6); (b)(7)c discussed how Protocols #112-2014 (NRD-952) and #115-2016 (NRD-999) by (b)(6); (b)(7)c will be amended to align with the findings of Protocol #113-2015 (NRD-964) by (b)(6); (b)(7)c

# 6. Training

The Chair provided training titled "Ethics of Animal Use in Research." (b)(6); (b) informed the IACUC that in 1966, Life Magazine published an edition that had pictures of animals being used in research, and it was this edition that lead to a number of the animal research use regulations under the AWA.

The Chair informed the IACUC that the next Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International inspection and review will be next year (2017). (b)(6); (b) inquired about whether SSC Pacific received a specific date or time of year for the AAALAC inspection and review. (b)(6); (b) said it could be spring or fall, and that (b)(6); (b) said there was no need to delay the inspection until the animals return to the Bay Side facilities. The Chair informed the IACUC that the current Program Description that would be used during the AAALAC inspection and review, covered both the Bay Side and NMAWC facilities.

When discussing Replacement, Reduction and Refinement (The Three Rs) requirements for animal use, (b)(6); (b) added that it is not good for investigations to use the same animals for multiple protocols to get at a 'reduced' number of animal subjects.

# 7. Animal Care and Use Program Review

The Chair led the IACUC through the SSC Pacific Program Review. (b)(6); (b) recommended sending the list of points of contact for Occupational Health to (b)(6); (b) (b)(6); to determine if there are any changes needed.

The Chair informed the IACUC that the program needs to identify a point of contact for receipt of Personnel Occupational Health forms because the old point of contact, (b)(6); (b)(7)c (b)(6); is no longer at SSC Pacific. Until that person is identified, personnel are to give their Occupational Health forms to (b)(6); (b)(7)c

The Chair asked that those members that inspect the Fish Houses, do so with extra scrutiny as there is a desire to improve on conditions in the Fish Houses. (b)(6); (b)(7)c informed the IACUC that one Fish House is being renovated this year and the other will be renovated next year.

# Subj: MINUTES OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE MEETING, 6 OCT 2016

# 8. Facilities Inspection

The Administrator reviewed the outstanding inspection items from the 31 March 2016 inspection. The Chair informed the Administrator that the shelves in (b)(3); (b)(7)e secured to the wall, so that item can be removed from the list. The Administrator reported that there are a few reoccurring deficiencies that need to be addressed, such as the improper labeling of sprayers and bottles containing chemicals.

The IACUC members then broke up into teams and performed their inspection.

9. The meeting was adjourned.

All committee members reviewed and approved these minutes via electronic mail.

(b)(6); (b)(7)c		
		10-25-2016
(b)(6); (b)(7)c	Alternate Chair	Date
	(b)(6); (b)(7)c	
Approved by:		10.26.16
(b)(6);	(b)(7)c Director, Navy Marine 1	Mammal Program, Code 71005, Date

Distribution:

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Committee Members (w/o encl)

Blind Copy: 71000 71510 71500 (Ltr 715/05) 84343 (2)

Written by: Mr. Michael Letourneau, 71500, x0887 Typed by: Lisa Root, 715, x33252, 25 Oct 16

Reviewed by:

# **IACUC MEETING SIGN-IN SHEET**

60<1 Date: 3<del>1 MAR</del> 2016

		Date: 3-1 WIPH			
(b)(6): (b)(7)c	Name		Signat	ure	
(b)(6); (b)(7)c					
_					
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-					
-					
-					
_					
		. /	/		
(b)(6):	(b)(7)c		/		
(b)(6);					

# DOD SEMIANNUAL PROGRAM REVIEW / FACILITY INSPECTION

# Signature Sheet / Minority Opinions Form

Organization: Navy Marine Mammal Program Code 71500

Dates of Review: 31 MAR 2016

There were / were not (circle one) minority opinions in this semiannual review

IACUC Member	SIGNATURE	DATE	MINORITY OPINION YES NO
(b)(6); (b)(7)c			

NOTES:

# **SECTION V - REMARKS**

- 1.b.(2)(b) VetLab Pharmacy: Nolvasan container on windowsill (sink in small equipment room) is expired and needs appropriate sticker.
- 1.b.(2)(b) (b)(3); (b) Nolvasan drum outside of the building on the back porch needs proper labeling.
- 1.b.(2)(e) VetLab: No paper towels at sink in the small equipment room.
- 1.b.(2)(g) (b)(3); Med Shack: Trainers using animal (Jell-O) microwave for personal food.
- Need separate facilities for human food preparation and animal food preparation and storage.
- Women's Locker Room: Locker room where fish buckets are
  - temporarily being cleaned needs cleaning.
  - 1.b.(3) (b)(3); : Spare gate chains needed for enclosures assigned to breeding crew.
  - 7.a. NAB! Trainers reporting that enclosure and walkway planks are missing.
  - 9.b.(1) (b) Fish House Freezer: General clutter/disorder.
  - 9.b.(1) Fish House Freezer: Fish on the floor of freezer.
  - 9.b.(1) Fish House Freezer: Ice build-up on floor especially around the entrance to freezer.
  - 9.b.(1)(b) Fish House Freezer: Fish boxes left open; unused fish exposed.
  - 9.b.(1)(b) Fish House Freezer: Freezer door does not latch, using bucket to keep door closed.
  - 9.b.(1) (b) Fish House: Brooms, scrub brushes and squeegee are resting on the floor while the brackets for the brooms and brushes are being used to hang the scales.
  - 9.b.(1)(b) Fish House: Water hoses coiled on the floor.
  - 9.b.(1) (b) Fish House: Several animal buckets with holes in the bottom and emitting foul odors. (3);
  - 9.b.(1) (b) Fish House: Algae build-up on walls under sinks.
  - 9.b.(1) Fish House: Thawed fish (2 capelin) on bucket rack.
  - 9.b.(1) (b) Fish House: Large plastic bleach container and metal support in washing area has a significant amount of algae build-up.
  - 9.b.(1)(b) Fish House: Weather stripping for the bottom of the door in washing are is missing resulting in a large gap at the bottom of the door.
  - 9.b.(1)(b) Fish House: Bleach sprayers not labeled.
  - 9.b.(1) Fish House: Algae on the hose on the ground near the entrance to fish house.
  - 9.b.(1) Fish House Freezer: Something biological (?) unwrapped and on top of fish boxes in the freezer.
  - 9.b.(1) (b) Fish House Freezer: Mats on the floor in the freezer are uneven and buckled and could be potential trip hazard.
  - 9.b.(1) Fish House Freezer: Pallets are against the wall of the freezer.
  - 9.b.(1) (b) Fish House: Algae growth around hose of the bucket washing sink.
  - 9.b.(1) (b) Fish House: Disposal/grinder housing is very rusty with pieces of the metal cover breaking off.
  - 9.b.(1)(b) Fish House: Bleach stored in cabinet on wall with vitamins for the animals.
  - 9.b.(1) Fish House: Algae growth on walls in the disposal area.
  - 9.b.(1) Fish House: Large rust stains on the floor in several places (e.g., corners and under bucket (3).
  - 9.b.(1)(b) Fish House: Fish waste in the main drain.
  - 9.b.(1)(b)(3); (b): Ice machine on back porch needs service record tag.

#### **SECTION V - REMARKS**

- 9.b.(2)(b)(3); (b): Potable water hose hanging 4 6 feet underwater potential for contamination via holes or backflow if end of hose drops into water. Need to adequately secure the hose above the water level.
- 9.b.(4) VetLab Pharmacy: Cytology supply drawer expired swabs mixed in with non-expired swabs.
- 9.b.(4)(a) VetLab Pharmacy: Janitorial closet mops and brooms are resting on the floor need hooks for proper storage.
- 9.b.(4) VetLab: Sink in the water test room is scoured and rusty.
- 9.b.(4) VetLab: Two Chemsearch bottles need to be in secondary containment.
- 9.b.(4) VetLab: Some of the Betadine in the instrument room have expired.
- 9.b.(4)(a) VetLab Surgery Room: Mops on the ground rather then hung up.
- 9.b.(5) VetLab Pharmacy: Recycling can is overflowing and needs to be emptied.
- 9.b.(5) VetLab: Stain accumulation bin under the sink is 1 year old and should be thrown out after 9 months.
- 9.b.(6) VetLab Procedure Area: Birds roosting under roof of the floating procedure area.
- 12.a. VetLab: Expired culture tubes mixed in with non-expired tubes. Culture tubes that have expired need to be removed.
- 17. VetLab Dolphin Pool Area: General Clutter.
- 17. VetLab Bldg 51: Sink in the storage room does not work (the deionized water runs but not the main taps) and there is dirt all over the counter (from recent roof repair?).
- 19.a. VetLab Bldg 51: Broken floor tiles.
- 19.d. VetLab Dolphin Pool Area: Concrete braking up outside the western steps to Building 194 and could become a trip hazard.
- 19.f. VetLab (b)(3); A number of boxes on high shelves close to ceiling.
- 19.f. VetLab (b)(3); Open Ceiling tile in the back room of the archive room with a bucket underneath and the adjacent tiles have visible water damage (appears that the leak may have been repaired recently).
- 19.i. VetLab Necropsy: Specimen heads kept in plastic containers outside of the fume cabinets could off-gas and need to be properly stored.
- 19.i. VetLab (b)(3); Freezer 10 has an excessive amount of ice buildup.
- 20.a. VetLab Necropsy: General Clutter.
- 20.a. VetLab Necropsy: Boxes stacked high on overhead cabinets.
- 20.a. VetLab Necropsy: Sample refrigerator contains old samples need to be properly disposed of and refrigerator cleaned.
- 20.a. VetLab Necropsy: Band saw blades not properly stored currently hanging over the body of the saw.
- 20.a. VetLab Surgery Room: Crack in floor near the entrance to pharmacy.
- 20.a. VetLab Surgery Room: Vaporizer on the large animal ventilator is past due for inspection.
- 20.a. VetLab Surgery Room: Several pieces of surgical gear (e.g., catheter needles, forceps) are expired.
- 20.a. (b)(3); (b) General clutter in wetsuit shack.
- 20.a. Breeding training staff needs a shed to store lunch and personal gear currently using medical shack.

# **SECTION V - REMARKS** 20.e. VetLab: Biohazard chest freezer behind necropsy room (outside), currently does not have temperature gauge. In addition, the power source is unreliable in wet weather. Updated freezer with temperature gauge is needed and moved to a location out of the elements. 20.e. VetLab (b)(3); Biohazard bin in archive room has no date label on it. 20.g. VetLab Sea Lion Cabana: Shade tarp/roof is only covering half of the front/bay-side room. 20.g. VetLab Sea Lion Cabana: Minor wear on plastic webbing should be monitored.

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Dates of Review: 06 OCT 2016

There were / were not (circle one) minority opinions in this semiannual review

IACUC Member	SIGNATURE	DATE	MINORITY OPINION
	5,0,0,0,0		VEG NO
(b)(6); (b)(7)c			

NOTES: (b)(6); (b)(7)c of Navy Medical Center, San Diego and (b)(6); (b)(7)c of SSC Pacific were also present and were observers during the facilities inspection.

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There were / were not (circle one) minority opinions in this semiannual review

IACUC Member	SIGNATURE	DATE	MINORITY OPINION YES NO
(b)(6); (b)(7)c			120   110

NOTES: (b)(6); (b)(7)c of Navy Medical Center, San Diego and (b)(6); (b)(7)c of SSC Pacific were also present and were observers during the facilities inspection.

# Heating, Ventilation and Air Conditioning (HVAC) System Summary

as of Jul 2017

Summarize the heating, ventilation and air conditioning (HVAC) information for each animal facility, including all satellite facilities, indicating: a) source(s) of air, b) air recirculation rates if other than 100% fresh air, c) air exchange rates, d) relative pressure differentials, e) humidity control, and f) date of most recent measurement/evaluation. Include all animal holding rooms, (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment, etc.). Air exchange rates within animal holding rooms and cage washing facilities are required. Air exchange rates may be important to maintain air quality in other areas; however, measurements may be left at the discretion of the institution. Information may be provided in another format, providing all requested data is included. HVAC information should be provided from assessments obtained within the past 12 months.

Bldg/	Hee	Air Source	Treatment	Air	Dressure	Humidity	Date
Room No	Use	%Fresh/Recirculated	Filtered/Absorbers, etc.	Changes	Pressure	Control	Assessed
(b)(3); (b) (7)e	Pharmacy				-	N	
	Lab				-	N	
	Sub-sterile				-	N	
	Surgery				+	N	
	Small Equipment				-	N	
	Procedure				-	N	
	Large Equipment				-	N	
	Necropsy				-	N	
	Tissue Archive				-	N	

# Appendix 11 Aquatic Systems Summary\* – Part I

as of 31 Jul 2017

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities/rooms/enclosures. The following key will assist you in completing the form:

- (1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
- (2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
- (3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
- (4) Indicate water type, e.g., fresh, brackish, or marine.
- (5) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
- (6) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, etc. and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

#### Part I

		System Design							
Location (1)	Species (2)	Group / Individual (3)	Water Type (4)	Pre-treatment	Circulation (5)	Filtration (6)	Disinfection (e.g., UV, ozone)		
(b)(3);	Bottlenose Dolphin	G	Marine	N/A	N/A	N/A	N/A		
(b)(3);	Bottlenose Dolphin	G	Marine	N/A	N/A	N/A	N/A		
(b)(3);	California Sea Lion	G	Marine	N/A	N/A	N/A	N/A		

<sup>\*</sup>Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, etc.) should be available for review.

# Aquatic Systems Summary - Part II

Part II

Monitoring Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)									
Location (from Part I)	Temperature	Salinity	рН	NH4	NO₂	NO <sub>3</sub>	Dissolved O <sub>2</sub>	Total Dissolved gases	Other. Please List (2):
(b)(3);									Coliforms / E coli weekly
(b)(3);									Coliforms / E coli weekly
(b)(3);									Coliforms / E coli weekly

- (1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).
- (2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine, etc.

This information may be provided in another format, provided that all requested data is included.

# Appendix 12

# **Primary Enclosures and Animal Space Provisions**

as of 31 Jul 2017

Please complete the table below considering performance criteria and guiding documents (e.g. <u>Guide</u>, <u>Ag Guide</u>, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species and wildlife when reviewing biomedical, field and agricultural research studies.

\*For aquatic species, provide tank volume. \*\*Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to Determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Bottlenose Dolphin	Open Ocean Pens 30'x30'x8' (7200ft <sup>2</sup> )		9 CFR Ch.1, Part3, Subpart E: Specifications for the Humane Handling, Care, Treatment, and Transportation of Marine Mammals	All dolphins are enclosed in open-ocean floating net enclosures. Enclosures are composed of trex/wooden deck/walkway supported by custom fiberglass floats or EX Dock sections. The floating structure supports a 6" mesh net made of #48 nylon twine. The vertical dimension of the side net is 8'. Net stretch creates an effective maximum vertical dimension of >12'.
California Sea Lion	Open Ocean Pens Wet: 15'x24'x8' (2880 ft <sup>2</sup> ) Dry: 475ft <sup>2</sup>		9 CFR Ch.1, Part3, Subpart E: Specifications for the Humane Handling, Care, Treatment, and Transportation of Marine Mammals	Floating complexes are composed of a 15'x24'x8' suspended 4" mesh #48 nylon twine anti-fouling net seimming area and 475ft2 of deck dry haul out area. Six individual 24ft2 housing areas for animal separation adjoin the haul out area. Tenser TMpolygaurd 2" mesh plastic fencing surrounds the entire complex and a suncscreen is affixed over the haul out/individual housing areas. Individual housing dividers and gates are polyvinyl coated chainlink.

# Appendix 13 Cleaning and Disinfection of the Micro- and Macro-Environment as of 31 Jul 2017

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Other Comments	
Micro-environment				
Solid-bottom cages (Sea lion haul out areas)	High pressure saltwater house	Daily and as needed	Biosciences Division SOP#18: Animal Enclosure and Pier Area Cleaning, Sanitation, and Maintenance	
Suspended wire-bottom or slotted floor cages	High pressure saltwater house	Biweekly	Nets are monitored for fouling, invertebrate growth, and integrity by training staff bi-weekly. If necessary, nets are defouled with a high-pressure saltwater hose and repaired or replaced as needed.	
Cage lids (overhead sunscreens)	High pressure fresh or saltwater house	As needed		
Feeders (Feeding buckets)	Rinsed of fish scales and visible debris with high pressure, hot water. A solution of biodegradable enzymatic detergent in 120 degree Fahrenheit water is used to scrub all bucket surfaces and left in place for a minimum of ten minutes. After a thorough hot water rinse, all fish contact surfaces are sanitized by spray application of 200ppm sodium hypochlorite and allowed to air dry with the opening down on racks.	Daily	Biosciences Division SOP #7, Fish House Cleaning and Sanitation	
Watering Devices(Hydration tubes, sea lion tubs)	Dolphin hydration tubes and Sea lion water tubs are cleaned and filled daily	Daily		

Exercise devices and manipulanda used in environmental enrichment programs, etc.(Rub ropes, balls, toys)	High pressure hot fresh water sprayer	As needed	
Transport cages (Sea lion cages and Dolphin beaching mats)	High pressure saltwater, hand scrubbing, fresh water rinse	After use and as needed	Sea Lion Cages: Hand scrubbed with dilute sodium hypochlorite per gallon of water), or quaternary ammonium and rinsed with high pressure fresh water.  Dolphin beaching mats: Highpressure seawater spray followed by hand scrubbing with biodegradable enzymatic detergent and high-pressure seawater rinse.  ATCs: high-pressure spray, hand scrubbing with dilute sodium hypochlorite or biodegradable enzymatic detergent and highpressure rinse.
Operant Conditioning & Recording Chambers, Mechanical Restraint Devices (sea lion squeeze cages)	High pressure hose	Immediately after use	Hand scrubbed with dilute sodium hypochlorite (one ounce of sodium hypochlorite per gallon of water), and rinsed with high pressure fresh.
Tooth brushes, harnesses	Chlorhexidine, fresh water	Immediately after use	
Deck areas surrounding animal enclosures	High pressure hose, fresh water and scrubbing broom	Daily	

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Other Comments
	Macro-Env	vironment	
ANIMAL ROOMS			Activity logs posted outside all areas to record sanitation activities
Floors	High pressure hose and TechQuat (quaternary ammonium)	Weekly, before and after use	
Walls	High pressure hose and TechQuat	Weekly, before and after use	
Ceilings	High pressure hose and TechQuat	As Needed	
Ducts/Pipes	High pressure hose and TechQuat	As Needed	
Fixtures	High pressure hose and TechQuat	Daily	
CORRIDORS			NA
Floors			
Walls			
Ceilings			
Ducts/Pipes			
Fixtures			
SUPPORT AREAS (Necropsy)			
Floors	High pressure hose and TechQuat	After use	
Walls	High pressure hose and TechQuat	As needed	
Ceilings	High pressure hose and TechQuat	As needed	
Ducts/Pipes	High pressure hose and TechQuat	As needed	
Fixtures	Washed with TechQuat	Weekly or Monthly as needed	

SUPPORT AREAS (Clinical Laboratory)		
Floors	Mopped with TechQuat	Weekly
Walls	Washed with TechQuat	As Needed
Ceilings	Washed with TechQuat	As Needed
Fixtures – counters	Surfaces cleaned with chlorhexidine or TechQuat	Daily
SUPPORT AREAS (Fish Houses)		
Floors	Scrubbed with TechQuat, Sanitized with dilute bleach (sodium Hypochlorite)	Daily
Ceiling	High pressure washed with hot water and dilute bleach	As Needed
Ducts/pipes	High pressure washed with hot water and dilute bleach	As needed
Garbage disposal	Scrubbed with soap, rinsed with water. Sanitize with dilute bleach	Daily, after bucket washing
Brushes, scrub pads	Hot water rinse, sanitize with bleach	After each use
Bucket Racks	Scrubbed with soap, rinsed with water. Sanitize with dilute bleach	Weekly
IMPLEMENTS (note whether or not shared)		
Mops and buckets	Washed in detergent with bleach	Daily, after each use
Towels and linens	High pressure rinse with hot water and scrubbed with bleach	After each use
Medical procedure mats	Interior sprayed out/wiped with bleach	As needed
Vehicle(s) – trucks and boats	Interior sprayed out/wiped with bleach	As needed